PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW Washington, DC 20503**.

1. Agency/Subagency originating request
EPA, Office of Prevention, Pesticides & Toxic Substances

2. OMB control number b. ■ None
a. **2 0 7 0** - __ __ __ __ __ __ __ __

3. Type of information collection *(check one)*
a. ✔ New collection
b. **G** Revision of a currently approved collection
c. **G** Extension of a currently approved collection
d. **G** Reinstatement, **without change**, of a previously approved collection for which approval has expired
e. **G** Reinstatement, **with change**, of a previously approved collection for which approval has expired
f. **G** Existing collection in use without an OMB control number

For b-f, note item A2 of Supporting Statement Instructions

4. Type of review requested *(check one)*
a. ✔ Regular
b. **G** Emergency - Approval requested by: ____/___/____
c. **G** Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? **G** Yes ✔ No

6. Requested expiration date
a. ✔ Three years from approval date b.**G** Other Specify: ___/___/___

7. Title **Pesticides; Tolerance Processing Fees; Proposed Rule**

8. Agency form number(s) *(If applicable)* **EPA ICR #1915.01; Form currently being designed. Number not yet assigned.**

9. Keywords **Agricultural commodities, pesticides and pests, reporting requirments**

10. Abstract

The Food Drug and Cosmetic Act (FFDCA) requires the Environmental Protection Agency (EPA) to collect fees so that the tolerance processing program is self-sufficient. The statute requires EPA to collect fees that will, in the aggregate, be sufficient to cover the costs of evaluating tolerances for pesticide products. An economic analysis was performed in 1983 and, other than small annual incremental increases, tolerance fees have not kept pace with the increasing program costs. In addition, the Food Quality Protection Act of 1996 (FQPA) has changed the number of regulatory actions that now fall under the heading of "tolerance processing," along with the responsibilities associated with reviewing tolerance petitions and other tolerance actions. EPA has estimated the resources needed to process tolerance actions, both for petitioned tolerances and tolerances that now must be reassessed under FQPA. The Agency proposes to revise the current tolerance fee structure and sets new fee amounts that reflect today's processing costs.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*
a. __ Individuals or households d. __ Farms
b. **P** Business or other for-profit e. __ Federal Government
c. __ Not-for-profit institutions f. __ State, Local or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*
a. **G** Voluntary
b. ✔ Required to obtain or retain benefits
c. **G** Mandatory

13. Annual reporting and recordkeeping hour burden
a. Number of respondents 31
b. Total annual responses 31
1. Percentage of these responses collected electronically 0 %
c. Total hours requested 221
d. Current OMB inventory 0
e. Difference 221
f. Explanation of difference
1. Program Change New Program
2. Adjustment

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs
b. Total annual costs (O&M)
c. Total annualized cost requested
d. Current OMB inventory
e. Difference
f. Explanation of difference
1. Program change
2. Adjustment

15. Purpose of information collection *(Mark Primary With "P" and all others that apply with "X")*
a. __Application for benefits e. __Program planning or management
b. __Program evaluation f. __Research
c. __General purpose statistics g. **P** Regulatory or compliance
d. __Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. **Q** Recordkeeping b. **Q** Third party disclosure
c. ✔ Reporting
1. **Q** On occasion 2. **Q** Weekly 3. **Q** Monthly
4. **Q** Quarterly 5. **Q** Semi-annually 6. **Q** Annually
7. **Q** Biannually 8. ✔ Other **once per event**

17. Statistical methods
Does this information collection employ statistical methods?
Q Yes ✔ No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*
Name: **Angela F. Hofmann, Director or Regulatory Coordination**
Phone: 202-260-2922

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):
- (i) Why the information is being collected;
- (ii) Use of information;
- (iii) Burden estimate;
- (iv) Nature of response (voluntary, required for a benefit, or mandatory);
- (v) Nature and extent of confidentiality; and
- (vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Program Official **Angela F. Hofmann, Director** **Regulatory Coordination Staff (OPPTS)**	Date
Signature of Senior Official or designee **Joseph Retzer, Director** **Regulatory Information Division** **Office of Regulatory Management and Evaluation (OPPE)**	Date

Certification Requirement for Paperwork Reduction Act Submissions

5 CFR 1320.9 reads "As part of the agency submission to OMB of a proposed collection of information, the agency (through the head of the agency, the Senior Official or their designee) shall certify (and provide a record supporting such certification) that the proposed collection of information --

"(a) is necessary for the proper performance of the functions of the agency, including that the information to be collected will have practical utility;

"(b) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;

"(c) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined in the Regulatory Flexibility Act 5 U.S.C § 601(6)), the use of such techniques as:

> "(1) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;
> "(2) the clarification, consolidation, or simplification of compliance and reporting requirements; or collection of information , or any part thereof;
> "(3) an exemption from coverage of the collection of information, or any part thereof;

"(d) is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond;

"(e) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;

"(f) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;

"(g) informs potential respondents of the information called for under § 1320.8(b)(3); [see below]

"(h) has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;

"(i) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and

"(j) to the maximum extent practicable, uses appropriate information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public."

NOTE: 5 CFR 1320.8(b)(3) requires that each collection of information:

"(3) informs and provides reasonable notice to the potential persons to whom the collection of information is addressed of:

> "(i) the reasons the information is planned to be and/or has been used to further the proper performance of the functions of the agency;
> "(ii) the way such information is planned to be and/or has been used to further the proper performance of the functions of the agency;
> "(iii) an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden);
> "(iv) whether responses to the collection of information are voluntary, required to obtain or retain a benefit (citing authority), or mandatory (citing authority);
> "(v) the nature and extent of confidentiality to be provided, if any (citing authority); and
> "(vi) the fact that any agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

(a) TITLE: Pesticides; Tolerance Processing Fees; Proposed Rule
OMB #: 2070-(tbd)
EPA #: 1915.01

(b) ABSTRACT

The Environmental Protection Agency (EPA) is required by statute to collect fees to cover the costs of processing tolerances for pesticide products. EPA is required to charge tolerance fees that will cover all costs associated with processing tolerance actions, including filing a tolerance petition, and establishing, modifying, leaving in effect, or revoking a tolerance or tolerance exemption. The Agency currently has in place a fee system for tolerance petitions, but no similar system has been developed or implemented for tolerances that must be reassessed either through the reregistration program or as a part of tolerance reassessment mandated by the Food Quality Protection Act of 1996 (FQPA). Regulations are proposed to update the existing fee system for tolerance petitions and establish a new system for reassessed tolerances, both of which will impose separate fees for each tolerance associated with a chemical. In addition, the statute states that regulations may provide for waivers or refunds of fees, in whole or in part, when it is in the Agency's judgement such actions are warranted. Under current legislation, any tolerance activity may be conditioned upon the payment of such fees.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Authorizing legislation is contained in section 408(m)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FQPA (attachment A). This section states that EPA shall collect fees as will in the aggregate be sufficient to cover the costs of all tolerance services and other tolerance-related functions. Tolerance fees shall be collected for such activities as (A) acceptance for filing of a petition, (B) establishing, modifying, leaving in effect, or revoking a tolerance or exemption, (C) the acceptance for filing of an objection, or (D) the certification and filing in court of a transcript of the proceedings and the record of a judicial review. Current regulations outlining the Agency's fee schedule are found in Title 40 of the Code of Federal Regulations Part 180.33 (attachment B).

New Tolerance Petitions

At present, petitioners remit the appropriate fee with their tolerance petitions and supporting data to the Agency. There is no paperwork burden or form associated with this fee collection activity although it is mentioned within the context of the tolerance petitions ICR

entitled, “Tolerance Petitions for Pesticides on Food/Feed and New Inert Ingredients” (OMB No. 2070-0024, EPA No. 0597.05). Under the proposed regulation, the Agency does not intend to impose a paperwork burden for new tolerance petitions unless a waiver is sought (see below).

Reassessed Tolerances

FFDCA Section 408(q) is a new statutory requirement mandated by FQPA. This provision requires the Agency to review all existing tolerances and tolerance exemptions that were in effect before August 3, 1996. Fees now must be collected for this activity under the authority of section 408(m)(1)(B).

For chemicals that are already registered, tolerances have been added over the lifetime of the registration. Virtually all of these chemicals have multiple tolerances or exemptions established that must be reassessed and several chemicals have over one hundred tolerances. A minimal amount of information is needed prior to the reassessment of the tolerances. Registrant’s will be asked to identify which tolerances they would like to be included in the reassessment. This information will determine the Agency’s workload and the fee charged.

Fee Waiver or Refund Requests

Current legislation allows EPA to grant fee waivers or refunds to those persons it deems deserving. FFDCA section 408(m)(1) provides this authority. EPA has proposed to grant fee waivers for several categories of tolerances, such as those for biological pesticides (except plant-pesticides), minor uses, or emergency exemptions under FIFRA section 18. Other tolerance fee waivers will be granted on a case-by-case basis based on certain criteria. If a petitioner or registrant requests a fee waiver or refund based on the criteria set forth by the Agency, certain information is needed to make the necessary determination.

2(b) Use/Users of the Data

Reassessed Tolerances

Under the proposed regulation, registrants of chemicals with existing tolerances will be asked to indicate on a prepared form their willingness to continue the support of each tolerance and remit the appropriate fee. The form (under development) will be used by the Agency for billing, payment, and tracking activities. The information provided will be used for planning and evaluation purposes. For example, a registered pesticide chemical may have 50 uses and 50 established tolerances. Based on the characteristics of the active ingredient, it may be apparent, prior to the actual reassessment of all of the tolerances, that the risk will exceed the new FQPA safety standard. A registrant may, therefore elect not to support certain uses by not paying the necessary tolerance fee. EPA will use this information and thus not include these uses in its risk assessment.

Fee Waiver or Refund Requests

EPA will continue the practice of granting fee waivers on a case-by-case basis to those applicants that cannot or should not have to pay. In addition to including specific fee waivers in its proposal, the Agency has revised and expanded the criteria for granting fee waivers for safer products, products that are in the public's interest, and to those registrants who demonstrate an economic hardship. Each waiver/refund request must be accompanied by a processing fee. This fee will be returned if the request is granted. Conversely, if the request is denied, the fee will be forfeited and the petitioner or registrant must remit the appropriate tolerance fee.

An updated Pesticide Registration (PR) Notice (attachment C) outlining the revised criteria will be made available in draft form for public comment. The PR Notice will be sent to all persons who hold pesticide product registrations and will inform them of what materials the Agency needs to evaluate a fee waiver or refund request. The Agency will use the information to determine whether a fee waiver or refund is warranted.

3. THE RESPONDENTS AND THE INFORMATION REQUESTED

3(a) Respondents/SIC Codes

The appropriate 3-digit Standard Industrial Classification (SIC) codes are 286 and 287.

3(b) Information Requested

(i) Data Items

New Tolerance Petitions

Petitioners are not required to submit any paperwork with respect to the tolerance fee. If a fee waiver is sought, the required information and materials are outlined in a separate section below.

Reassessed Tolerances

For tolerances that are scheduled to be reassessed, the registrant will be sent a form with the registrant's name and address pre-printed. The registrant only will need to complete this section to indicate an error or name or address change. The pesticide active or inert ingredient, PC code, established tolerances or exemptions, and date of registration will also be pre-printed. The registrant will be instructed to check-off those tolerances it wishes to be included in the Agency's risk assessment and those it does not want to support. In addition, there will be a space to indicate that a fee waiver or refund is sought. The registrant must also indicate the total amount of fee that is due, and the check number. If a fee waiver is sought, the required information and materials are outlined in a separate section below.

In some instances, there is more than one registrant that holds a technical registration for an active ingredient. In these cases, all of the registrants are collectively responsible for the tolerance fee. The Agency will indicate on the filing form all of the registrants of technical material. Space will be provided for an individual registrant to indicate 1) that they have

contacted the other registrants, and 2) whether they or another named registrant is remitting the fee.

Fee Waiver or Refund Requests

Economic hardship. Both petitioners of new tolerances and registrants of existing tolerances may request tolerance fee waivers or refunds. A registrant or petitioner who wishes to request a fee waiver or refund based on economic hardship will be required to submit sales information, operating costs and net income in order to qualify. It must demonstrate that the expected or actual annual number of acre-treatments is less than the annual number of acre-treatments which would be required to generate sufficient revenue to pay back the registrant's costs within three years.

The fee waiver request must include reasonable estimates for the following variables: (1) the registrant's total costs of any required studies and fees, (2) the revenue received by the registrant for the volume of pesticide necessary to treat one acre of crop (*i.e.*, one acre-treatment), and (3) the expected number of acre-treatments to be made annually with the pesticide at full market potential. A pay period of three years, and an after-tax rate or return on sales of 10% are fixed standards in the pay back calculation. The costs of any required studies should be itemized by study.

Estimates for the following parameters used by the applicant to calculate the expected number of annual acre-treatments are also required: (1) acres of crop grown, (2) total number of acres treated for the pest or pests, (3) average number of applications per growing season, and (4) expected or actual market share of the pesticide product under consideration.

Public interest. A petitioner or registrant who wishes to request a fee waiver or refund based on a public interest finding must fully substantiate the public interest nature of the individual request. Those respondents basing their fee waiver request on the distinction that their product has been determined as a safer pesticide under EPA's Reduced Risk Pesticide Program should submit Agency confirmation of the safer classification, and reference materials that were submitted to the Agency as part of this program. (Clearance for the collection activity associated with the Reduced Risk Pesticide Program is covered under the ICR entitled, "Application for New or Amended Registrations;" OMB No. 2070-0060; EPA No. 0277.10.)

Other requests can include, but are not limited to, the following types: 1) an important public health use; 2) a pest control chemical that is innovative and/or will significantly reduce a current environmental or human risk from alternative controls; or 3) a pesticide that is an essential part of an integrated pest management program or a biologically integrated pest management program or a biologically integrated alternative for pest control, and results in a net reduction in the pesticide chemical applied with conventional application methods. There are no specified criteria for these types of requests.

(ii)
Respondent Activities

New Tolerance Petitions

The only activity for the respondent is the one-time burden of reading and understanding the revised regulation. If a fee waiver is sought, the required activities are outlined in a separate section below.

Reassessed Tolerances

A registrant of an existing tolerance will be sent a cover letter, filing form, fee schedule, a list of other registrants of the same active ingredient (if applicable), and set of instructions on how to fill out the form and determine the appropriate fee due. Activities in which the registrant must engage in order to comply with this regulation include the following. If a fee waiver is sought, the required activities are outlined in a separate section below.

- Read revised regulation. This is a one-time burden.

- Read the instructions that accompany the form. Review the pre-printed information for accuracy.

- If more than one registrant is responsible for the fee, plan activities for contacting the other companies and coordinating the response and payment.

- Complete the form.

  ✔ Make necessary corrections to pre-printed material.

  ✔ Indicate which tolerances will be supported and those which have had their fees waived by the Agency (*e.g.* a minor use tolerance).

  ✔ Determine the appropriate fee that is due. Indicate on the form if a check has been sent (include check number), or, if in the case of multiple registrants, what payment arrangements have been made.

  ✔ Sign and date the form.

- Submit form and payment.

- Maintain a copy of the form in the company files. Although this is not required, the Agency assumes that most companies will retain this information as a common business practice.

Fee Waiver or Refund Request

If the petitioner of a new tolerance or a registrant of an existing tolerance wishes to request a fee waiver, it must undertake the following in addition to the activities listed above:

- Read the revised PR Notice.
- Compile and submit the necessary materials to support request.
- Indicate on the form that a waiver or refund is requested and that the required materials are enclosed or have been otherwise submitted to the Agency.
- Maintain a copy of the information submitted in the company files.

4. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a)
Agency Activities

- For a food use chemical that is subject to tolerance reassessment, prepare and send each registrant a bill which will include a cover letter, the tolerance reassessment form, the fee schedule, a list of co-registrants (if applicable), and instructions. Also identify in the cover letter a contact person to answer any questions a respondent may have.
- Review the submissions for completeness and accuracy. Record information provided by respondents into a tracking system. Make any identified corrections to the master computer files.
- Review and evaluate any fee waiver requests. Notify registrant of decision and refund monies if necessary.
- Verify payments. Cross check payment information from Financial Management Division.
- Transmit information to appropriate Management and Science divisions.
- Store the data. Microfilm all forms, listings, telephone conversations, *etc.* for archiving.

4(b) Collection Methodology

Bills will be sent to respondents via certified mail. Response forms will be returned by mail directly to the Agency; fee payments will be sent to the Financial Management Division in Pittsburgh, Pennsylvania. Work on the tolerance petition or reassessment will not begin until headquarters receives confirmation that payment has been made. All letters, bills, mail receipts, forms, petitions, and other types of correspondence will be tracked electronically. The Agency is exploring the feasibility of incorporating the tracking into its current systems. If this approach is not practical, a stand-alone tracking system will be developed.

Procedures for evaluating fee waiver and refund requests will not change. Information and materials submitted to justify a fee waiver or refund request are screened for completeness by

the receiving division. Economic data are sent to the economics division for analysis. Decisions are made rather quickly, usually within several weeks, and the petitioner or registrant is notified often by telephone and by mail. If the waiver or refund is granted, the waiver fee is returned.

4(c) Small Entity Flexibility

In most instances, small businesses will not be affected by this collection activity. Petitioners wishing to establish new tolerances on food use chemicals and registrants of existing active ingredients are basic producers of technical grade pesticides, and generally are large, multi-national chemical companies. Any company wishing to add a new food use to their label must generate sufficient data to support the tolerance, something smaller companies are not always financially able to do. For the few mid-size or small businesses that would like to add a new food use and provide the data for the establishment of a tolerance, or are responsible for the support an existing tolerance, EPA has made several provisions to reduce the burden incurred. These include such things as providing blanket fee waivers for minor uses or biological pesticides, or considering waiver requests based on economic hardship.

4(d) Collection Schedule

For new tolerances, there is no set schedule. The fee collection activity is conducted once per event, that is, whenever a tolerance petition is submitted to the Agency. For a tolerance that is to be reassessed, the schedule is also once per event. However, registrants will be notified in advance of when their payment is due. Bills for the remittance of tolerance fees will be sent at the beginning of each fiscal year to those registrants whose chemicals are scheduled for reregistration and tolerance reassessment during that year.

5. NON-DUPLICATION, CONSULTANTS, AND OTHER COLLECTION CRITERIA

5(a) Non-duplication

Not applicable. No other federal agency or EPA program is collecting this information. In addition, no other federal agency or EPA program is collecting fees for the processing of pesticide tolerances.

5(b) Consultations

Since the enactment of the FQPA in 1996, the Agency has been engaged in an extensive public participation process with regard to the implementation of the FQPA mandates. As a part of that process, the Agency has consulted with stakeholders with regard to the FQPA mandate associated with the establishment of these fees and the related proposed rule, and expects to continue these discussions during the comment period.

5(c) Effects of Less Frequent Collection

Since this collection activity is conducted only once per event, there is no practical way EPA can reduce the frequency of the collection.

5(d) General Guidelines

This collection activity complies with the guidelines for information collections under the Paperwork Reduction Act (PRA).

5(e) Confidentiality and Sensitive Questions

(i) Confidentiality

EPA does not believe that the information requested for tolerance fees or waiver/refund requests for such fees is confidential business information (CBI). However, all data and/or information submitted to the Agency in conjunction with this proposed rule may be claimed as trade secret, or commercial or financial information and will be protected from disclosure under FIFRA section 10 and the associated regulation as contained in 40 CFR Part 2, Subpart B. Information claimed as CBI is protected from public disclosure unless the Administrator determines that disclosure is in the public interest. The Office of Pesticide Programs routinely handles CBI data and personnel are familiar with security procedures in accordance with provisions of the FIFRA Confidential Business Security Manual to ensure confidentiality. If any information is submitted that respondents claim as confidential, the Agency will employ the established procedures for handling such material.

(ii) Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB circular A-108.

6. ESTIMATING BURDEN AND COST OF THE COLLECTION

Since the collection of tolerance fees has not included tolerance reassessment, the numbers provided are not reflective of any actual program values. These estimates, however, are based on the Agency's experience with other fee collection activities (e.g., reregistration fees and maintenance fees) and are reflective of registrant feedback as to the amount of time it has taken to fill out a short form and undertake other related activities. Upon renewal of this ICR, the Agency will be able to substitute actual values and better hone both its respondent and Agency burden estimates.

6(a) Estimating Respondent Burden and Costs

All petitioners and current registrants associated with a new or existing tolerance will need to familiarize themselves with the new regulations and waiver criteria. EPA assumes that every registrant of a food-use pesticide will want to familiarize him or herself from the outset, thus this burden is considered a one-time burden that will occur in the first year. This initial burden is expected diminish substantially once the rule is in place. Companies will only need to refer to the fee tables for the latest fee amount. There are an estimated 216 basic producers of food-use

pesticides. EPA estimates that it would take an individual one hour to completely read and comprehend the new rule.

The bulk of the burden results from the requirement for a registrant of existing tolerances to submit the tolerance reassessment billing form. Lines 2, 3, 4, and 6 in the table below estimate the burden associated with filling out and responding to the tolerance reassessment form. A company will need to fill out one form per pesticide chemical. The statute requires the Agency to complete its tolerance reassessment activity within ten years of enactment, with one third of all the tolerances reassessed in the first three years, two-thirds within six years, etc.. According to EPA's published schedule, 469 pesticides + 817 inert chemicals will need tolerances reassessed within the ten-year time frame. Also, according to the Agency's schedule, 228 chemical tolerances will be reassessed by 1999. This means that 228 bills will be sent out and 228 forms will need to be returned in the first year of this ICR. EPA plans to reassess the tolerances for 93 chemicals in the second three-year period--a respondent burden of 31 forms annually. Total responses for lines 2, 4, and 6, for the initial year of the ICR is 259 and will be 31 in the subsequent two years.

Some registrants will have an additional burden, either because they share generic responsibility with another producer of an active ingredient (line 3), or because they may wish to submit a request for a fee waiver or refund (line 5). For line 3, EPA estimates that approximately 5% of the chemicals have multiple registrants. Lines 1 and 5 include the burden for all potential respondents, that is, of both petitioners of new tolerances and registrants of tolerances to be reassessed. Therefore, the only burden of this collection activity that will go beyond the year 2006 will be for petitioners of new tolerances who wish to request a fee waiver and must submit materials pursuant to the criteria outlined in the PR Notice.

TABLE 1: FIRST YEAR RESPONDENT BURDEN AND COST ESTIMATES

		Burden Hours (per year)			Total	
	COLLECTION ACTIVITY	Mgmt.	Tech.	Cler.	Hours	Costs[1]
1	Read regulation	1.0			1.0	$ 114
2	Read form instructions		0.5		0.5	$ 39
3	Contact and coordinate response with other registrants, if applicable	1.5			1.5	$ 171
4	Complete form		0.3		0.3	$ 20
5	Compile materials for waiver or refund request, if desired		2.0		2.0	$ 154
6	Store/maintain information			0.2	0.2	$ 7

FIRST YEAR BURDEN:

(line 1)

1.0 Hours x 216 Responses = 216 Hours

(lines 2,4,6)

1.0 Hours x 259 Responses= 259 Hours

(line 3)

1.5 Hours x 13 Responses = 20 Hours

(line 5)

2.0 Hours x 30 Responses = 60 Hours

TOTAL 1st YEAR BURDEN = 555 Hours

FIRST YEAR COSTS:

(line 1)

0.5 hours x $114 (mgmt.) x 216 responses = $ 12,312

[1] Hourly costs of $114/hr. (managerial), $77/hr.(technical), and $35/hr. (clerical) are based on the industry labor rates given in the ICR Handbook, adjusted to 1993. Inflation for wage rates was obtained from the "Survey of Current Business," United States Department of Commerce.

(lines 2,4,6)

0.8 hours x $77 (tech.) x 259 responses = $ 15,955

0.2 hours x $35 (cler.) x 259 responses = $ 1,813
(line 3)

1.5 hours x $114 (mgmt.) x 13 responses = $ 2,223
(line 5)

2.0 hours x $77 (tech.) x 30 responses = $ 4,620

TOTAL 1st YEAR COSTS = $ 36,923

TABLE 2:
SUBSEQUENT ANNUAL RESPONDENT BURDEN AND COST ESTIMATES

		Burden Hours (per year)			Total	
	COLLECTION ACTIVITY	Mgmt.	Tech.	Cler.	Hours	Costs[2]
2	Read form instructions		0.5		0.5	$ 39
3	Contact and coordinate response with other registrants, if applicable	1.5			1.5	$ 171
4	Complete form		0.3		0.3	$ 20
5	Compile materials for waiver or refund request, if desired		2.0		2.0	$ 154
6	Store/maintain information			0.2	0.2	$ 7

ANNUAL BURDEN:

(lines 2,4,6)

1.0 Hours x 31 Responses = 31 Hours

(line 3)

1.5 Hours x 2 Responses = 3 Hours

(line 5)

2.0 Hours x 10 Responses = 20 Hours

TOTAL ANNUAL BURDEN = 54 Hours

ANNUAL COSTS:

(lines 2,4,6)

0.8 hours x $77 (tech.) x 31 responses = $1,910

0.2 hours x $35 (cler.) x 31 responses = $ 217

[2] Hourly costs of $114/hr. (managerial), $77/hr.(technical), and $35/hr. (clerical) are based on the industry labor rates given in the ICR Handbook, adjusted to 1993. Inflation for wage rates was obtained from the "Survey of Current Business," United States Department of Commerce.

(line 3)

1.5 hours x $114 (mgmt.) x 2 responses = $ 342

(line 5)

2.0 hours x $77 (tech.) x 10 responses = $ 1,540

TOTAL ANNUAL COSTS = $ 4,009

6(b) Estimating Agency Burden and Cost

The bulk of the Agency's burden is the development, mailing, and tracking of the tolerance reassessment billing form. This burden will end in the year 2006 upon the completion of tolerance reassessment.

For the Agency, line 1 in the table below estimates the burden associated with mailing the billing form filling out and lines 2, 4, 5, and 6 with reviewing the form after it is returned. Line 3 includes the burden for all potential respondents, that is, of both petitioners of new tolerances and registrants of tolerances to be reassessed who indicated that they wish to apply for a fee waiver or refund.

TABLE 3: ANNUAL AGENCY BURDEN AND COST ESTIMATES

		Burden Hours/per year			Total	
	COLLECTION ACTIVITY	Mgmt.	Tech.	Cler.	Hours	Costs[3]
1	Mail cover letter, forms, etc. for billing.	2.0	16.0	8.0	26.0	$1,232
2	Review submitted forms, resolve discrepancies, answer questions		1.5	0.2	1.7	$ 88
3	Review submitted waiver or refund requests. Notify requestor of decision		2.0		2.0	$ 110
4	Enter data into tracking systems		0.5		0.5	$ 28
5	Verify payment		0.3		0.3	$ 17
6	Store/maintain information			0.2	0.2	$ 5
	TOTAL	2.0	20.3	8.4	30.7	$1,480

FIRST YEAR BURDEN:

(lines 1,2,4,5,6)
28.7 hours x 259 responses = 7,433 hours
(line 3)

2.0 hours x 30 responses = 60 hours

TOTAL FIRST YEAR BURDEN = 7,493 Hours

FIRST YEAR COSTS:

(lines 1,2,4,5,6)
2.0 hours x $76 (mgmt.) x 259 responses = $ 39,368

18.3 hours x $55 (tech.) x 259 responses = $ 260,684

8.4 hours x $25 (cler.) x 259 responses = $ 54,390

[3] Government wage rates of $76/hr. (managerial), $55/hr. (technical), and $25/hr. (clerical) are based on 1993 federal pay scale for a GS-15, GS-13, and GS-7, step 5 employee, respectively, including benefits and overhead.

(line 3)

2.0 hours x $55 (tech.) x 30 responses = $ 3,300

TOTAL FIRST YEAR COST = $ 357,742

SUBSEQUENT ANNUAL BURDEN:

(lines 1,2,4,5,6)
28.7 hours x 31 responses = 890 hours
(line 3)

2.0 hours x 10 responses = 20 hours

TOTAL ANNUAL BURDEN = 910 Hours

SUBSEQUENT ANNUAL COSTS:

(lines 1,2,4,5,6)
2.0 hours x $76 (mgmt.) x 31 responses = $ 4,712

18.3 hours x $55 (tech.) x 31 responses = $ 31,202

8.4 hours x $25 (cler.) x 31 responses = $ 6,510
(line 3)

2.0 hours x $55 (tech.) x 10 responses = $ 1,100

TOTAL ANNUAL COST = $ 43,524

6(c) Total Burden Hours And Costs / Master Table

The estimated total burden and cost for the information collection activities contained in the proposed rule are displayed in Table 4.

TABLE 4: TOTAL BURDEN AND COST ESTIMATES

	TOTAL ESTIMATES	
	Hours	Costs
Applicant - First Year	555	$ 36,923

Annual	54	$ 4,009
Agency - First Year	7,493	$ 357,742
Annual	910	$ 43,524

For the purposes of determining the annual burden to respondents during the ICR's initial approval period, which EPA expects to be for 3 years, EPA has annualized the First Year burden by taking the excess burden in the first year, dividing it by 3, and then adding it to the projected burden from the Subsequent Year line. The resulting burden, as illustrated in Table 5, represents the annualized burden for this ICR during its initial three year approval period. When the ICR is subsequently renewed, the total annual burden will be reduced to the subsequent year annual burden.

TABLE 5 -- ANNUALIZED RESPONDENT BURDEN

	Hours	Costs
First Year - Annualized [(555-54)÷3] & [(36923-4009)÷3]	167	$ 10,971
Subsequent Annual	54	$ 4,009
Total	221	$ 14,980

6(d) Burden Statement

The public reporting burden for this collection of information is estimated to average 2.0 hours per response. According to the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to read the new regulation, review instructions, plan activities, assemble pertinent materials, and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information that is subject to the PRA unless the Agency displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9. This ICR is for a collection activity contained in a proposed rule, so the Agency will provide the OMB control number when the ICR is approved by OMB.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, OP Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 401 M Street, S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of

Management and Budget, 725 17th Street, NW, Washington, DC 20503, marked "Attention Desk Officer for EPA." Please submit your comments in accordance with the comment period provided in the preamble to the proposed rule and be sure to identify EPA ICR #1915.01 in any correspondence.

ATTACHMENTS FOR THE INFORMATION COLLECTION
(This information is not available electronically - Please see the public record)

A: Section 408(m) of the Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996

B: Title 40 of the Code of Federal Regulations Part 180.33

C: Draft Pesticide Registration (PR) Notice 98-X regarding Criteria for Waiver of Fees Associated with Tolerance Actions